Social Behavior Law and Ethics

For the students of
Pharmacy Technicians
(Category-B)

Second year **Paper 2**

PUNJAB PHARMACY COUNCIL

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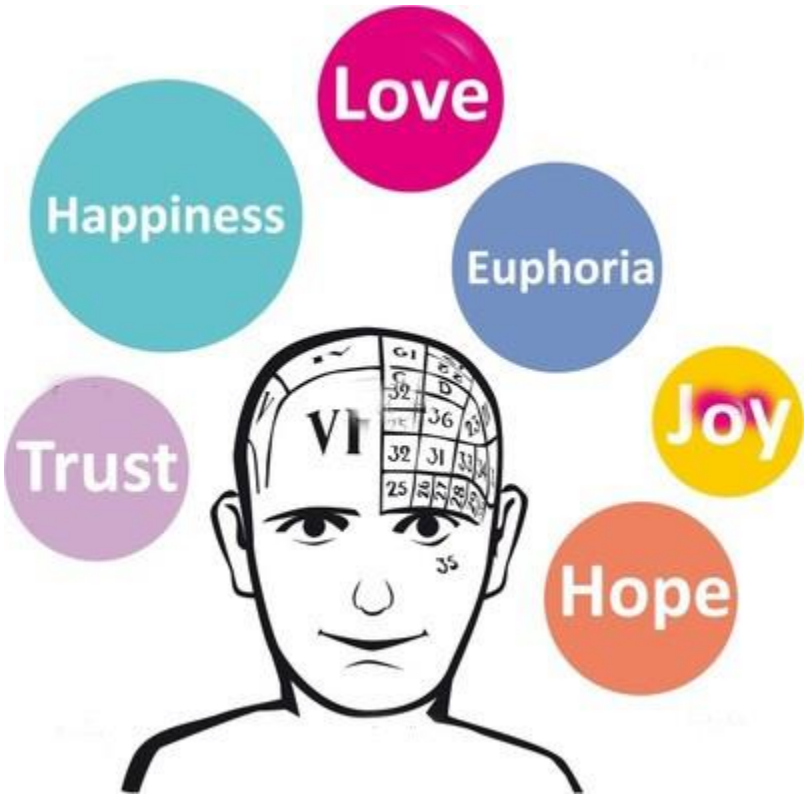
An Introduction To Behavioral Sciences



An Introduction To Behavioral Sciences

Behavioral Sciences

It deals with the study of human behavior using principles of psychology, sociology and anthropology in conditions of health and disease.

There are three main categories as follows

Psychology

It is the study of human mind and personality along with the role played by them in maintaining health or causing disease.

Sociology

It deals with the understanding of the influence of society on health & disease and includes role or family, gender issues, socioeconomic status, social policies.

Anthropology

It is the study of effects of evolutionary history, geographic distribution, cultural background and racial classification in the matters of health and disease.

Importance Of Behavioral Sciences

Behavioral sciences adds to the knowledge of physician and helps in practicing holistic medicine because psychology tells about the mind of patient and sociology and anthropology illustrates the evolution of human spirit.

Social Behavior

Social behavior is behavior directed towards society, or taking place between, members of the same species.

Principles Of Social Behavior

- Social behavior is goal oriented
- Social behavior represents a continual interaction between the person and the situation.
- The goals of our social behaviors function at different levels e.g. day-to-day, current, long-term
- Persons and situations influence one another in a number of ways
- Community and different organization level

Developmental Stages Of Life

1. Infant (Birth Till 8 Months)

- ❖ Check things by putting in mouth
- ❖ Mother love
- ❖ Development of trust

2. Early Childhood (8 Months To 3 Years)

- ❖ Master in specific skill
- ❖ Self autonomic

- Shame

3. Play Age (3 Years To 5 Years)
- Initiative to work, play etc.
- Purpose

4. School Age (6 Years To 12 Years)
- Superior or inferior complex
- Competence
- Increase learning ability

5. Adolescence (12 Years To 18 Years)
- What we do
- Finding own identity
- Devotion

6. Young Adulthood (18 Years To 35 Years)
- Affiliation
- Love
- Marriage
- Job
- Management skill
- Expand relation
- Isolation
- Rage
- Grudge
- Leg pulling

7. Middle Adulthood (35 Years To 55/65 Years)
- Stagnation of personality (stability)
- Control family
- Creative and meaningful work

8. Late Adulthood (55/65 Years To Rip)
- Integrity (feeling that life has meaning)
- Despair
- Wisdom

Hereditary Cultural And Environmental Influences On Behavior

Social Influences

Social influence occurs when someone's emotions, opinions, or behaviors are affected by others.

Hereditary Cultural Influences On Behavior

Culture make us different from animals in a way that our dressing, eating and way of living is different and much better then animals which increases the complexity of human behavior due to the influence of these cultural aspects.

E.g. The behavior according to way of living,

Culture of marriage in our society influences the human behavior in the following ways.

1. Restriction of free sexual relation like animals
2. Economic stability (earning, job etc)
3. Family relation and system originates

How "Hereditary Cultural Changes" Change The Human Behavior

Genetics also referred to as heredity. The influence of heredity on human behavior can be huge if a child doesn't have encouraging/ motivational parents as he is growing up. For example, if you have two kids, and you let someone to adopt one from them. If one set of parents doesn't cater to that child's emotional needs, and teach that child how to control anger and what to do with it, but the other set of parents do, you're going to see a major difference in how both children grow up and interact in society. Hence heredity culture plays an important role in developing or influencing the behavior.

Environmental Influences

These are the factors or influencing stimuli that affect the human and surround them.

Physical Environment

Physical environment is used those environmental factors that can be seen and visualized.

Malnutrition

Makes people rude and psychology disturbs.

Noise

Creates anxiety and anger leading to quarreling.

Drugs (Narcotics)

Drugs especially narcotics effect temporarily and permanently leading to bad social relations.

TV

Television and commercials can change the basic thoughts and views of any person.
Community define person behavior, a person behave according to behaviors of community.

Psychological Environment

- A person if expected to be like his parents and he makes his behavior similar to parents.
- Different attitudes of parents or younger's and elders brothers he make a child depressed and can suffer from complexes.
- Siblings (bro &sis) have psychological influences each other and have many things in similar.

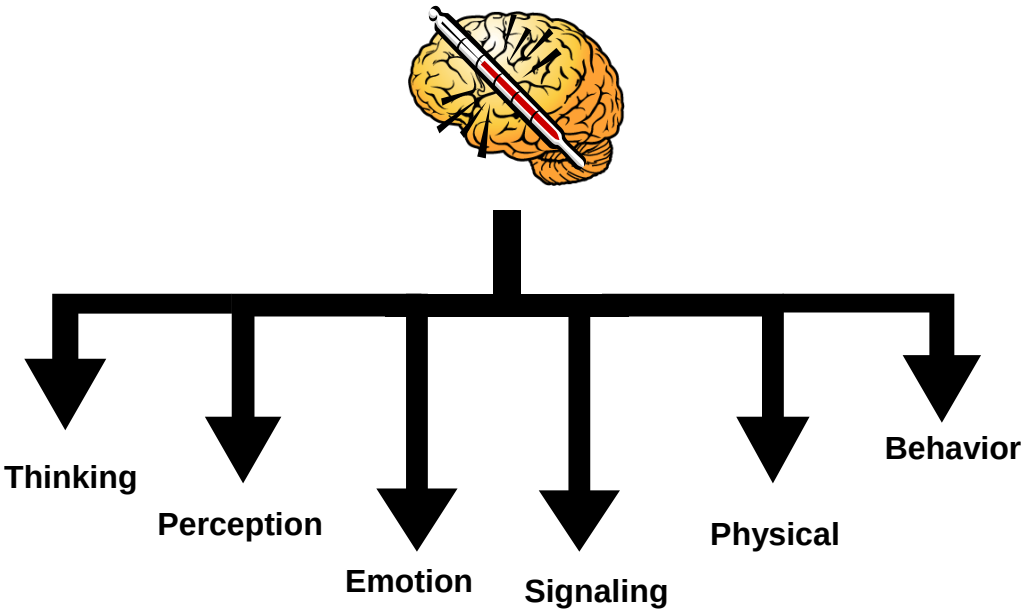
Mental Health And Applied Psychology

Mental Health

Mental health is a state of well-being in which the individual realizes his or her own abilities, can survive with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to his or her community".

It is definitely not easy to avoid feeling stressed, and pressure can build up in many areas of life (socially, in school, at home, and while making big life decisions). Worrying about these pressures is normal. But feeling very sad, hopeless or worthless might be a sign of a mental health problem.

Mental illness can occur when the brain (or part of the brain) is not working well or is working in the wrong way. When the brain is not working properly, one or more of its 6 functions will be disrupted



Applied Psychology

Applied psychology is the use of psychological principles and theories to overcome problems in real life situations. Many areas of our lives and society have been influenced and changed by the often-unnoticed application of psychological principles.

Psychotherapy

A common form of treatment for many mental health problems is psychotherapy also called talk therapy. Psychotherapy is the practice of spending time with a psychological professional trained to help diagnose and treat mental and emotional problems or other mental health problems.
Psychotherapy aims to increase the individual's sense of his/her own well being. Usually it is provided by a mental health professional such as a clinical psychologist.

Psychotherapy Helps People With A Mental Disorder

- To understand the behaviors, emotions, and ideas that contributes to his or her illness and learning how to modify them
- To understand and identify the life problems or events like a death in the family, a loss of a job, or a divorce
- To recover a sense of control and pleasure in life
- To learn problem solving techniques and skills

Generally psychotherapy is recommended whenever a person is disturbed due to relationship or work issue or a specific mental health concern, and he or she is upset for longer than a few days. Psychotherapy is most successful when the individual enters therapy on their own and has a strong desire to change.

Therapy can be given in a variety of formats, including:

Individual

This therapy involves only the patient and the therapist.

Group

Two or more patients may participate in therapy at the same time. Patients are able to share experiences and learn that others feel the same way and have had the same experiences.

Couples

This type of therapy helps husband and wife to understand why their loved one has a mental disorder, what changes in communication and behaviors can help, and what they can do to help him or her.

Family

This type of therapy helps family members to understand what they can do to help their family member if someone has a mental disorder.

Importance Of Communication Skills

Importance Of Communication Skills

Definition Of Communication

The word communication means the act or process of giving or exchanging of information, signals, or messages as by talk, gestures (movement of part of the body), or writing.

Why Is Communication Important?

It is widely accepted that communicating the correct information and advice to patients is as important as providing the medicine itself.

The patient often measures quality by how well the physician listens, and how thoroughly the physician explains the diagnosis and treatment options, and how well the physician involves the patient in decisions concerning his or her care.

Physician should communicates with his patients in a proper manner, it is the best way to treat the patient rather than using complicated medical terminologies, which may not be helpful to the patient.

Successful medical encounters require effective communication between the patient and the physician. "Success" implies that the patient and physician have developed a "partnership" and the patient has been fully educated in the nature of his or her condition and the different methods to address the problem. This allows the patient to be actively involved in the decision-making process and establishes agreed upon expectations and goals.

Importance of communication has always been realized in all times. Communication plays very important role in all aspects of treatment. Patient and physician have to communicate with each other, exchange information, make decisions, talking about new ideas, plans and best way to achieve the treatment goals.

Verbal And Non Verbal Communications

Verbal Communication

These are vital skills for the doctors and can be mastered through practice. Verbal communication is a technique used by the doctor to give all the information and advices in the language of the patient that can be easily understand by the patient.

Non-Verbal Communication

The communication other than verbal language is non - verbal communication. It involves the body movements, face expressions, postural moves to express and communicate with the people. It is called non-verbal communication.

Principles Of Verbal And Nonverbal Communication

Following are basic Principles of Verbal and Nonverbal Communication

- Know your audience (e.g. patient)
- Know your purpose (e.g. asking about the medical history)
- Know your topic
- Guess or be aware objections (e.g. understanding current situation of patient)
- Communicate a little at a time
- Ask questions in several ways
- Develop a useful way to get feedback
- Use multiple communication techniques

Communication Skills And Doctor Patient Relationship

The best way to get rid of diseases and to get a good and reliable treatment the first thing is a better relationship between doctor and patient. It requires the best professional skills by a doctor about human behavior, his abilities to listen and behave in a way that is understandable by the patient.

Having good communication skills is essential for doctors to establish good doctor patient relationship. Health service research on doctor patient relationship has become an important area of interest for both medical researchers and administrators alike.

Good doctor patient communication is important and has multiple impacts on various aspects of health outcomes. The impacts included…

- Better health outcomes
- Reduce complaints
- Higher compliance to therapeutic regimens in patients
- Higher patient and clinician satisfaction
- Decrease in malpractice risk
- Reduce unnecessary investigation

The responsibility of effective communication lies with the physician because he is not only expected to know the language of the patient but also he has to educate the patient who is mostly unaware of medical and technical knowledge.

Adaptations Of Electronic Technology

Life has become so fast and sharp and the world has become a global village, this all globalization of world and centralization of national and international projects are managed by the electronic technology and tools.

Even this technology is equally important for peace to war, from family affairs to international affairs; from health to business management etc. yesterday a calculator was known as a big invention while today it is just a very much basic tool or object for primary

students to a very small business.

Use Of Electronic Technology In Pharmaceutical Industry

The use of electronic technology is widely spreader in pharmaceutical industry electronic tools and equipments are used in every department from receipt of raw material up till the product is finished. Electronic technology used in each process of manufacturing of a product.

Use Of Electronic Technology At Pharmacies

In medical stores and pharmacies, from receiving the goods and medicine, up to storage are selling of products and medicines all done by electronic equipments, even some pharmacies keep the information about their regular customers, their disease medication and other treatments and this is all done by electronic equipments like computer.

Use Of Technologies In Health

Use of Technology is used in different departments of health e.g. Thermometer, X-ray, MRI, Hospitals and laboratories, and even on pharmacies use of electronic goods such as computers are widely used in health professions.

Adoption For Individualized Needs

This means how a health care provider will adjust; tailor his communication skill or methodology according to the individual people reaching him, as well of the people accessing him would not have the same literary rate, mental caliber or mental status. So one must take care and access the situation and adjust him accordingly to make the communication process better and more effective.

Some patients visiting the health care provider may need a moral or psychological support so the physician or pharmacist shall boost their moral and avoid any state of hopelessness being achieved by their mind.

Fundamental Writing Skills

Basic writing skills are essential not just in school and the workplace, but in everyday life and interactions as well. It can be difficult to master these skills, especially when they aren't introduced and practiced from an early age.

Skills You Need To Write

There are many basic components and skills necessary for good writing, the most important and fundamental being grammar, language rules, vocabulary and style.

Grammar and language rules deal with the order and structure of language, including accepted rules and guidelines for constructing sentences that convey ideas most effectively.

There are different kinds of words in every sentence, meaning each word has its own job to do. This is true in every language. In fact, these fundamental parts of speech have the same job in every language. Knowing the parts of speech in English can make it helpful to learn other languages, e.g. noun, verb etc.

Punctuation marks are symbols that indicate the structure and organization of written language.
We use vocabulary, an internal library of words and their meanings, to shape the thoughts and feelings into language. Vocabulary constantly expands as a person learns and communicates.
Style is a person's unique writing voice and tone, and is used to help express individuality and communicate the desired ideas and concepts to the reader in the most engaging and meaningful way possible.

Basic Steps To Improve Writing Skills

Strong writing skills come from practice and determination. No one is born an excellent writer. Learning to be an excellent writer takes a lot of time and practice. Anyone can be a good writer if they are determined enough.

One easy way for practice grammar, vocabulary and punctuation skills is to consult workbooks to improve writing skills. Reading can also help in providing examples of solid, polished writing with well-developed voice and style.

Importance Of Writing Skills

The ability to write your thoughts and ideas clearly is crucial for personal, social and professional success and confidence for many reasons. Writing helps you express yourself by encouraging you to find the right words for feelings and ideas that might seem intangible otherwise. It also enhances your ability to understand your own ideas and explain them to others more effectively by making them visible and permanent.

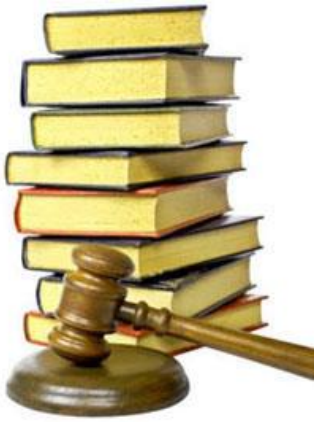
Introduction To Law And Ethics

Introduction To Law And Ethics

Pharmacy Law

Pharmacy law is a body of information about drugs, drug distribution and drug therapy. The information is used by legislators, administrative agencies and courts of law to assure that all parties to whom responsibilities have been assigned meet those responsibilities.

The Purpose Of Pharmacy Law



Pharmacy law protects patients from harm that might occur if medications were used in ways that unreasonably increase the risk of their causing harm. Some pharmacy laws relate to all drugs and the hazards of using them for therapeutic reasons.

Other laws relate to a subset of drugs that have the potential for abuse, and these laws seek to restrict inappropriate use while not interfering with legitimate use. The primary goal of pharmacy law is to address the question: "How far should government go to protect people who use medications of their own choices in drug therapy?"

To fully appreciate pharmacy laws, it is important to understand what is required and why, as well as understand that pharmacy law is dynamic and can be changed to protect the public in ways that extend beyond the status quo. Most laws exist for a reason, and pharmacy laws are no exception to this general rule. Restrictions on the use of chemicals as drugs and restrictions on individual practice of pharmacy exist because the open market would fail to protect the public if any old chemical could be used as a drug and if anyone could practice pharmacy. The public would be unnecessarily exposed to risks of harm from dangerous chemicals and dangerous dispensers of them. This prospect of harm is a reason to regulate, and it justifies legal restrictions on drug distribution.

The Structure Of Pharmacy Law

Pharmacy law is regulated at the federal and state levels. Federal rules primarily relate to the drug product, while state rules primarily relate to the people who practice pharmacy and the practice sites with in which they perform their professional duties.

As a general rule, pharmacists are required to fulfill with the most restrictive law, if both state and federal law address a specific issue and if they conflict on that issue. For example, if under federal law a particular drug is not restricted to prescription-only sale, but under state law there is such a restriction, pharmacists may not sell the drug without a prescription, because state law would be stricter.

Pharmacy Ethics

Pharmacy ethics is branch of medical ethics that provides a framework for pharmacists to use in resolving questions about what ought to be done in pharmacy practice.

Some Code Of Ethics For Pharmacists

Pharmacists are health professionals who assist individuals in making the best use of medications. This Code, prepared and supported by pharmacists, is intended to state publicly the principles that form the fundamental basis of the roles and responsibilities of pharmacists.

- A pharmacist respects the covenantal relationship between the patient and pharmacist.
- A pharmacist promotes the good of every patient in a caring, compassionate, and confidential manner.
- A pharmacist respects the autonomy and dignity of each patient.
- A pharmacist acts with honesty and integrity in professional relationships.
- A pharmacist maintains professional competence.
- A pharmacist respects the values and abilities of colleagues and other health professionals.
- A pharmacist serves individual, community, and societal needs.
- A pharmacist seeks justice in the distribution of health resources.
-

Legal Guidelines In Health Care

Here are legal guidelines for a Pharmacist/ Pharmacy Technician/ Assistant Pharmacist regarding the pharmacy

- Any pharmacist exercising their professional role must be registered, safe and competent to practice.
- Pharmacist must be aware that the patient is the primary focus.
- Pharmacist must be trained in respect of their area of operation.
- Pharmacist must ensure that dispensing is carried out accurately.
- Each prescription must be critically reviewed before dispensing to ensure that the medicines are safe and in the best interest of the patient.
- The pharmacist must contact the prescriber regarding medicines and patient issues if needed.
- Patients must be given complete details regarding their medicines at the time of dispensing, so that they fully understand what the medicine is and what it is for.
- Proper information must be given to the patient regarding the safe storage of their medicine.
- The medicine dispensed must be of suitable quality, fit for use suitably packaged and labeled manner.
- Pharmacists should ensure that the necessary facilities, equipment and materials are present.
- Pharmacy should be clean and weighing must be accurate.

Beside the above-mentioned responsibilities, pharmacist must keep in mind the following guidelines also…

Narcotics Drugs

Narcotics drugs should be carefully stored, because the demand of these drugs is high and could be stolen easily. At the time of closing these drugs should be checked on regular basis.

Poisonous Drugs

Poisonous drugs must be in lock. These drugs should be sold only to needy patients and it should be conformed that the patient is well aware from this poisonous drug. On the boxes of poisonous drugs, there should be "Poisonous" written with red ink and in bold font with a "skull and bones" picture.

On the label, there should be antidote medication written for the purpose of emergency treatment if someone takes this poison mistakenly. Sales register must be used for the entry of sold poisons, in which, there must be poison name with the buyer name entered.

Pregnancy Related Drugs

Be careful regarding the storage and sale of abortifacient drugs (drugs that induces abortion) and contraceptives drugs (birth control drugs to prevent pregnancy in women). These drugs should be stored in separate cabinet. Record of these medicines should be maintained according to the law.

Expiry Control

Keep the drugs in front of shelves, which are about to expire, and the drugs having the long expiry should be kept backside. Inform the company about the drugs which are going to expire near future before two to three month of expiry date. It is prohibited to store expired medicine in the pharmacy.

Bill Warranty

This is the specific written text bill, which is issued to the buyer at the time of sale from the whole-seller or pharmaceutical company. The purpose of warranty is to ensure the buyer that, the medicine is manufactured according to the law and standards. The whole-seller/ pharmaceutical company would be responsible if any type of violation found in the manufacturing or standards.

Drug name, batch number, company name, quantity, warrantor name, signature and address should be mentioned on the bill warranty. There should be no drug in pharmacy without warranty and the drugs record should be computerized.

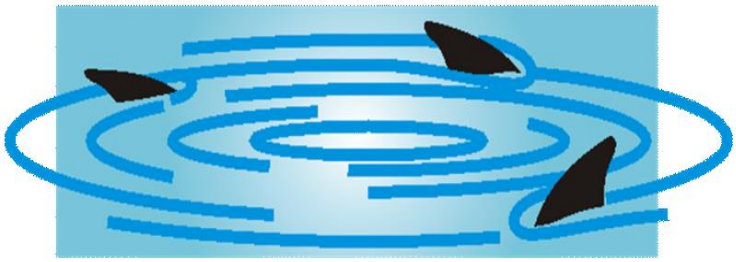
Risk Management

What Is A Hazard?

Anything or any condition, which has the potential to cause injury or harm to health

- Noise
- Airborne contaminants
- Moving vehicles
- Manual handling
- Spills
- Naked flames

HAZARD



This is a HAZARD. No one can be hurt because there is no one here.

What Is A Risk?

The likelihood that exposure to a hazard will result in injury, disease or other loss occurring

RISK

This is RISK.
Someone may be harmed here.

Types Of Hazards

- Physical
- Chemical
- Mechanical
- Biological

- Radiation
- Psychological

Risk Management Plan

Risk management involves an assessment of the risks a pharmacy faces, followed by the development of ways to eliminate or control those risks to prevent setbacks from happening.

Following steps are involve in risk management

1. **Risk analysis/ Risk Assessment**
2. **Risk evaluation**
3. **Risk acceptance**
4. **Risk control**
5. **On-going evaluation**
6. **Risk Communication**

Risk Analysis/ Risk Assessment

In this step we identify the system, hazards and possible harms.

Risk Evaluation/ Risk Quantification

After the risk analysis, we estimate, justify and document risk level e.g. probability/ severity.

Risk Acceptance

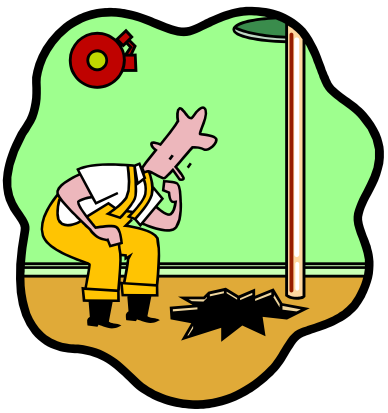
In this step we compare risk with acceptance criteria and finalize the acceptance or rejection or the risk.

Risk Control

In the step of risk control, we estimate the costs to control the risk define and take suitable actions.

On-Going Evaluation

This is important step to control upcoming risks; we continuously monitor new harms, risk levels and update plans and actions accordingly.



Risk Communication

It is not enough to learn about risks and control them. One must communicate that information to health care professionals and patients. If the communication is successful, people will become aware of the risk and modify their behavior to avoid safety hazards. Without such communication, there is no hope that patients will change their behavior.

An introduction to Manual of Drug Laws

Different Definitions

Definitions: In this Act, unless there is anything repugnant in the subject or context,

Drug

"Drug" includes--

(i) any substance or mixture of substances that is manufactured, sold, stored, offered for sale or represented for internal or external use in the treatment, mitigation, prevention or diagnosis of diseases, an abnormal physical state, or the symptoms thereof in human beings or animals or the restoration, correction, or modification of organic functions in human beings or animals, not being a substance exclusively used or prepared for use in accordance with the ayurvedic, unani, homoeopathic or biochemic system of treatment except those substances and in accordance with
such conditions as may be prescribed;

(ii) abortive and contraceptive substances, agents and devices, surgical ligatures, sutures, bandages, absorbent cotton, disinfectants, bacteriophages, adhesive plasters, gelatine capsules and antiseptic solutions;

(iii) such substances intended to be used for the destruction or repulsion of such vermin, insects, rodents and other organism as cause, carry or transmit disease in human beings or animals or for disinfection in residential areas or in premises in which food is manufactured, prepared or kept or stored;

(iv) such pesticides as may cause health hazard to the public;

(v) any substance mentioned as monograph or as a preparation in the Pakistan Pharmacopoeia or the Pakistan National Formulary or the International Pharmacopoeia or the British Pharmacopoeia or the British Pharmaceutical Codex or the United States Pharmacopoeia or the National Formulary of the United States, whether alone or in combination with any substance exclusively used in the unani, ayurvedic, homoeopathic or biochemic system of treatment, and intended to be used for any of the purposes mentioned in sub-clauses (i), (ii) and (iii), and

(vi) any other substance which the Federal Government may, by notification in the official Gazette, declare to 'be a "drug" for the purposes of this Act;

Adulterated Drugs

"Adulterated drugs" means a drug--

(i) which consists in whole or in part of any filthy, putrid or decomposed substance or which contains any foreign matter, vermin, worm, rodent or insect; or

(ii) which has been manufactured, packed, or held under unsanitary conditions whereby it [has] been contaminated with dirt, filth or any other foreign matter or whereby it may have been rendered injurious to health; or

(iii) The container of which releases any poisonous or deleterious substance which may render the contents injurious to health; or

(iv) Which bears or contains as an ingredient a substance other than the prescribed substance; or

(v) With which any substance has been mixed or packed so as to reduce its quality or strength or for which any substance has been substituted wholly or in part;

Misbranded Drug

"Misbranded drug" means a drug--

(i) which is not labelled in the prescribed manner; or

(ii) on the label or labelling of which any word, statement or other matter or information required by the rules to appear on the label or labelling is not prominently placed with such conspicuousness (as compared with other words, statements, designs, or devices on the label or labelling) and in such terms as may render it likely to be read 'and understood by the ordinary individual under customary conditions of purchase and use; or

(iii) which is not labelled with such directions for use and such warnings against use in indications where its use may be dangerous to health, or against unsafe dosage or duration of administration or application in such manner and form as are necessary for the protection of users or as may be prescribed; or

(iv) the label or container of which, or anything accompanying which, bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular; or

(v) which is so coloured, coated, powdered or polished that damage is concealed, or which is made to appear of better or greater therapeutic value than it really is; or

(vi) which is manufactured according to the specifications of a particular pharmacopoeia or any other document as may be prescribed and the label does not bear the name of that pharmacopoeia or document;

Spurious Drug

"Spurious drug" means a drug--

(i) which purports to be a drug but does not contain the active ingredient of that drug; or

(ii) Which purports to be the product of a manufacturer, place or country of whom or of which it is not truly a product; or

(iii) Which is imported or exported or sold or offered or exposed for sale under a particular name while actually it is another drug; or

(iv) The label of which bears the name of an individual or company purporting to be its manufacturer or producer which individual or company is fictitious or does not exist;

Counterfeit Drug

"Counterfeit drug" means a drug the label' or outer-packing of which is an imitation of, or resembles or so nearly resembles as to be calculated to deceive the label or outer-packing of a drug of another manufacture;

Sub-Standard Drug

"Sub-standard drug' means a drug which is not of specifications.

Batch

"Batch" means a quantity of any drug produced during a given cycle of manufacture;

Batch Number

"batch number" means a designation printed on the label of a drug that identifies the batch and permits the production history of the batch, including all stages of manufacture and control, to be traced and reviewed;

Expiry Date

"Expiry date" means the date stated on the label of a drug after which the drug is not expected to retain its claimed efficacy, safety, quality or potency or after which it is not permissible to sell the drug;

Generic Name

"Generic name" means the non-proprietary, scientific or official name of a drug as approved by the Federal Government;

Government Analyst

"Government analyst" means a Federal Government Analyst or Provincial Government Analyst appointed under Section 16;

Inspector

"Inspector" means a Federal Inspector or a Provincial Inspector appointed under Section 17;

Label

"Label" means a display of written, printed or graphic matter upon the immediate container, or the outside container or wrapper of a drug package;

Labeling

"Labeling" means all labels and other written, printed or graphic matter accompanying any drug;

Manufacture

(r) "manufacture", in relation to a drug, means all operations involved in the production of the drug, including processing, compounding, formulating, filling, packing, repacking, altering, ornamenting, finishing and labelling with a view to its storage, sale and distribution, but does not include the compounding and dispensing or the packing of any drug in the ordinary course of retail business or on a prescription of a registered medical practitioner or dentist or of a veterinarian and "to manufacture" shall be construed accordingly;

Provincial Quality Control Board

Provincial Quality Control Board: (1) Each Provincial Government shall set up a Provincial Quality Control Board consisting (3f such members, including a Chairman, as that Government may appoint from time to time.

(2) The Chairman and other members of the Provincial Quality Control Board shall hold office during the pleasure of the Provincial Government, on such terms and conditions as that Government may determine.

(3) 'The provincial Government shall appoint a person to be the Secretary of the Provincial Quality Control Board and provide the Board with such staff as the Provincial Government may consider necessary.

(4) The Provincial Quality Control Board shall with the approval of the Federal Government and by notification in the official Gazette make regulations to regulate the conduct of its business.

(5) The following shall be the powers and functions of the Provincial Quality Control Board, namely:--

(a) to inspect any premises where any drug is being or is to be, manufactured or sold and to recommend to the appropriate authority the cancellation or suspension of the licence to manufacture or sell drugs granted to any person who is found to be contravening, or to have contravened, any of the provisions of this Act, or the rules;

(b) to scrutinize the reports of Provincial Inspectors in respect of contraventions of this Act and 'reports of the Government Analysts in respect of drugs Sent to them by the Provincial Inspectors for test and analysis and issue instructions to the Inspectors to the action to be taken on such reports:

Provided that the Provincial Quality Control Board may specify the class of cases in which a Provincial Inspector may make a complaint to the Drug Court, or take any other action, without the specific instructions of the Board;

(c) to exercise all the powers of an Inspector under this Act and the rules; [.]

(d) to advise the Provincial Government on ways and means to ensure quality control of drugs manufactured in the Province; and

(e) to ascertain the names of such directors, partners and employees of the company, corporation, firm or institution who are prima facie responsible for the commission of any offence under this Act or the rules and allow an Inspector in institute prosecution only against such persons;

(f) to conduct annual validation of all instruments in the provincial drug testing laboratories and to recommend measures to upgrade such laboratories, if required;

(g) identify and accredit on payment of fee other laboratories in the Province with suitable facilities and expertise;

(h) to conduct training programs to update Government Analysis and for improving their knowledge according to latest analytical method and technology; and

(i) to submit and monthly report of decisions and activities to the Federal Government

(6) The Provincial Quality Control Board may entrust any of its powers or functions under sub-section (5) to any one or more of its members.

Government Analysts

The Federal Government or a Provincial Government may, by notification in the official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be the Federal Government Analysts or, as the case may be, Provincial Government Analysts, for such areas and in respect of such drugs or classes of drugs as may be specified in the notification:

Provided that no person who has any financial interest in the manufacture, import, export or sale of drugs shall be so appointed:

Provided further that a person serving under the Federal Government or another Provincial Government shall not be so appointed without the previous consent of that Government.

Inspectors

The Federal Government or a Provincial Government may, by notification in the official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Federal Inspectors, or, as the case may be, Provincial Inspectors for the purposes of this Act within such local limits as it may assign to them respectively:

Provided that no person who has any financial interest in the manufacture, import, export or sale of any drug shall be appointed:

Provided further that a person serving under the Federal Government or another Provincial Government shall not be .so appointed without the previous consent of such Government.

Powers of Inspectors

(1) Subject to the provisions of section 19 and of any rules made in this behalf, an Inspector may, within the local limits for which he is appointed, and in any other area within the permission of the licensing authority,-

(a) inspect any premises-wherein any drug is manufactured, the plant and process of manufacture, the means employed for standardising and testing the drugs and all relevant records and registers;

(b) inspect any premises wherein any drug is sold or is stocked or exhibited for sale or is distributed, the storage arrangements and all relevant records and registers;

(c) take samples of any drug which is being manufactured, or being sold or is stocked or exhibited for sale or is being distributed;

(d) enter and search, with such assistance, if any, as he considers necessary, any building, vessel or place, in which he has reason to believe that an offence under this Act or any rules has been or is being committed or may continue to be committed;

(e) call any person to be present as witness in the course of search or seizure or in connection with any other matter where the presence of witnesses is necessary;

(f) seize such drug and all materials used in the manufacture thereof and any other articles, including registers, cash memos, invoices and bills, which he has reason to believe may furnish evidence of the commission of an offence punishable under this Act or any rules;

(g) require any person to appear before him at any reasonable time and place to give statement, assistance or information relating to or in connection with the investigation of an offence under this Act or the rules:

Provided that the exemptions under Sections 132 and 133 of the Code of Civil Procedure, 1908 (Act V of 1908), shall be applicable to requisitions for attendance under this Clause;

(h) lock and seal any factory, laboratory, shop, building, store-house or godown, or a part thereof, where any drug is or is being manufactured, stored, sold or exhibited for sale in contravention of any of the provisions of this Act or the rules;

(i) forbid for a reasonable period, not exceeding four weeks or such further period, which shall not be more than three months, as the Inspector may, with. the approval of the Provincial Quality Control Board, the Central Licensing Board, the Registration Board, or the licensing authority, as the case may be, specify, any person in charge of any premises from removing or dispensing of any drug, article or other thing likely to be used in evidence of the commission of an offence under this Act or the rules; and

(j) exercise such other powers as may be necessary for carrying out the purposes of this Act or any rules:

Provided that the powers under causes (f) to (j) shall be exercisable only by an Inspector specifically authorised in this behalf, by an order in writing, by the Government appointing him, subject to such conditions as may be specified in such order:

Provided further that the power under clause (h) may be exercised by an Inspector not authorised as aforesaid where the contravention is of a provision which requires a licence to be obtained for the manufacture, storage or sale of a drug.

(2) The provisions of the Code of Criminal Procedure, 1898 (Act V of 1898), in so far as they are not inconsistent with the provisions of this Act, shall apply to searches and seizures made under this Act.

Procedure For Inspectors

(1) Where an Inspector seizes any drug or any other article under section 18, he shall tender a receipt therefore in the prescribed form.

(2) Where an Inspector takes a sample of a drug for the purpose of test or analysis, he shall intimate such purpose in writing in the prescribed form to the person from whom he takes it and, in the presence of such person unless he wilfully absents himself, shall divide the sample into four portions and effectively seal and suitably mark the same and permit such persons to add his own seal, if any, and mark to all or any of the portions so sealed and marked:

Provided that, where the sample is taken from premises whereon the drug is being manufactured, it shall be necessary to divide the sample into three portions only:

Provided further that, where the drug is made up in containers of small volume, instead of dividing a sample as aforesaid, the Inspector may, and if the drug be such that it is likely to deteriorate or be otherwise damaged by exposure shall, take three or four, as the case may be, of the said containers after suitably marking the same and, where necessary, sealing them:

Provided further that if the contents of one container are insufficient for the laboratory test and analysis, the Inspector may increase the number of the containers in order to make the sample sufficient for this purpose.

(3) The Inspector shall restore one portion of a sample so divided or one container, as the case may be, to the person from whom he takes it, and shall retain the remainder and dispose of the same within seven days as follows :-

(i) one portion of sample he shall send to the Government Analyst concerned for test and analysis;

(ii) the second he shall send to the chairman, Provincial Quality Control Board or the Central Licensing Board or the Registration Board, as the case may be; and

(iii) the third, where taken, he shall send to the warrantor, if any, named under the proviso to sub-section (3) of Section 32.

(4) Where an Inspector seizes any drug containing any filthy or putrid substance, vermin,

worm, rodent, insect or any foreign matter which is visible to the naked eye, and the sample is such that it cannot or need not be divided, he shall effectively seal and suitably mark the same and permit the person from whom he seizes the drug to add his own seal, if any, and mark to it and shall produce the same before the Drug Court or the Central Licensing Board or the Registration Board, as the case may be, before which proceedings are instituted or action is initiated in respect of the drug.

(5) Where an Inspector takes any action under section 18,--

(a) he shall as soon as practicable ascertain whether or not the drug contravenes any of the provisions of this Act and, it is ascertained that the drug does not so contravene, he shall forthwith revoke the order passed under the said section or, as the case may be, take such action as may be necessary for the return of the stock seized and payment for the samples taken, under intimation to the Board concerned;

(b) if he seizes the stock of the drug he shall, as soon as may be inform the Board concerned and take its order as to the custody thereof:

Provided that where a Federal Inspectors not competent to take action under section 30, he shall as soon as may be, report the matter and hand over the stock, if any, to the Provincial Inspector for further action under this Act.

(6) The Provincial Inspector on finding any contravention of this Act shall, unless the Board otherwise directs, always refer the case to the Provincial Quality Control

Board and seek orders as to the action to be taken in respect of such contravention.

(7) The Federal Inspector on finding any contravention of this Act for which he is authorised shall, unless otherwise directed, always refer the case to the Central Licensing Board or the Registration Board or any other authority as may be specified for the purpose and seek any further orders as to the action to be taken in respect of such contravention.

Prohibitions

Import, Manufacture And Sale Of Drug

(1) No person shall himself or by any other person on his behalf--
(a) export, import or manufacture for sale or sell ·
(i) any spurious drug;
(ii) any counterfeit drug;
(iii) any misbranded drug;
(iv) any adulterated drug;
(v) any substandard drug;
(vi) any drug after its expiry date;
(vii) any drug which is not registered or is not in
accordance with the conditions of registration;
(viii) any drug which, by means of any statement, design or device accompanying it or by any other means, purports or claims to cure or mitigate .any such disease or ailment, or to have any such other effect, as may be prescribed;
(ix) any drug if it is dangerous to health when used in the dosage or with the frequency, or,

for the duration specified, recommended or suggested in the labelling thereof; or
(x) any drug in contravention of any of the provisions of this Act or any rule;

(b) manufacture for sale any drug except under, and in accordance with the conditions of, a licence issued under this Act;

(c) sell any drug except under, and in accordance with the conditions of, a licence issued under this Act;

(d) import or export any drug the import or export of which is prohibited by or under this Act;

(e) import or export any drug for the import or export of which a licence is required, except under, and in accordance with the conditions of, such licence;

(f) supply an incorrect, incomplete or misleading information, when required to furnish any information under this Act or the rules;

(g) peddle, hawk or offer for sale any drug in a park or public street or on a highway, footpath or public transport or conveyance;

(h) import, manufacture for sale, or sell any substance, or mixture of substances, which is not a drug but is presented in a form or a manner which is intended or likely to cause the public to believe it to be a drug;

(i) sell any drug without having a warranty in the prescribed form bearing the name and batch number of the drug issued,--

(i) in the case of a drug manufactured in Pakistan, by the manufacturer holding a valid licence to manufacture drugs and permission to manufacture that drug or by his authorised agent;

(ii) in the case of an imported drug, by the manufacturer or importer of that drug or, if the drug is imported through an indentor by such indentor; and

(j) apply an incorrect batch number to a drug.

(2) Nothing in sub-section (1) shall apply to the manufacture or subject to prescribed conditions, of small quantities or any drug for the purpose of clinical trial examination, test, analysis or personal use.

Penalties

(1) Whoever himself or by any other person on his behalf:
(a) exports, imports, manufactures for sale or sells any spurious drug or any drug which is not registered;
(b) manufactures for sale any drug without a licence; or
(c) imports without licence any drug for the import of which a licence is required;

shall be punishable with imprisonment for a term which shall not be less than three years or more than ten years and with fine which may extend to one lakh rupees:

Provided that the Drug Court may, for any special reasons to be recorded, award a sentence of imprisonment for a term of less than three years.

(2) Whoever himself or by any other person on his behalf--
(a) imports, manufactures for sale or sells any counterfeit drugs; or
(b) gives to the purchaser a false warranty in respect of any drug sold by him that the drug does not in any way contravene the provisions of Section 23 and is not able to prove that, when he gave the

warranty, he had good and sufficient reason to believe the same to be true; or

(c) applies or permits to be applied to any drug sold, or stocked or exhibited for sale, by him, whether on the container or a label or in any other manner, a warranty given in respect of any other drug, or

(d) imports, manufactures for sales or sells any drug under a name other than the registered name; or

(e) exports, imports, manufactures for sale or sells any drug with which any substance, which should not actually be its component, has been mixed or packed so as to reduce its quality or strength or for which any such substance has been substituted wholly or in part;

shall be punishable with imprisonment for a term which may extend to seven years, and with fine which may extend to one lakh rupees.

(3) Whoever obstructs an Inspector in the exercise of any power conferred upon him by or under this Act, or disobeys the lawful authority of any Inspector, shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to ten thousand rupees, or with both.

(4) Subject to the provisions of sub-section (1), sub-section (2) and sub-section (3), whoever himself or by any other person on his behalf contravenes any of the provisions of this Act or any rule shall be punishable with imprisonment for a term which may extend to five years, or with fine which may extend to fifty thousand rupees, or with both.

(Note: Penalties could be change time to time by Government)

The Pharmacy Act, 1967

Definitions

In this Act, unless there is anything repugnant in the subject or context,

(a) `Approved' means approved under section 18 or, as the case may be, section 19;

(b) `*Central Council'* means the Pharmacy Council of Pakistan established under section 3;

(c) `*Council*' means a Pharmacy Council established under section 3;

(d) `*Medical Institution'* means an institution whose medical qualifications are recognized under the Medical Council Ordinance, 1962 (XXXII of 1962);

(e) `*Pakistan Pharmacists Association'* means the association registered under the Societies Registration Act 1860 (XXI of 1860) and known at the commencement of the Pharmacy (Amendment) Act, 1973 by that name;

(f) `*Pharmacist*' means a person who is registered under section 24 in register A and Register B.

(g) `Pharmacy Institution' means an institution whose qualifications of Pharmacy are recognized under this Act; and

(h) `*Provincial Council'* means the Pharmacy Council of a Province established under section 3.

Establishment of Pharmacy Councils

Within a period of one year from the commencement of this Act:

(a) The Central Government shall, by notification in the official Gazette, establish a Central Pharmacy Council to be known by the name of the Pharmacy Council of Pakistan; and

(b) Each provincial Government shall in like manner, establish a provincial Pharmacy Council to be known by the name of the province concerned.

(2) Each of the Pharmacy Councils established under sub section (1) shall be a body corporate having perpetual succession and common seal, with power, among others, to acquire, hold and dispose off property, and shall by its name sue and be sued.

Composition of Central Council

(1) The Central Council shall, subject to the provisions of sub section (2), consist of the following members, namely:

(a) The Director General of Health, Government of Pakistan, ex-officio, who shall, unless the Central Government appoints any other officer to be the President, also be the President of the Council;

(b) The officer, if any, appointed under clause (a) to be the President of the Council;

(c) Eight persons to be nominated by the Federal Government out of whom one from each province shall be nominated in consultation with the provincial Government concerned, one shall be a teacher of Pharmaceutics and one a teacher of Pharmaceutical Chemistry;

(d) One person from each province, to be nominated by the Federal Government so far as may be in consultation with the provincial Council concerned;
(e) One person, to be nominated by the Federal Government in consultation with the Pakistan Pharmacists Association; and

(f) The Drugs Controller, Government of Pakistan; and

(2) The Central Government may by notification in the official Gazette, increase or decrease the number of persons to be nominated by it under clause (c) of sub section (1).
Provided that the decrease in the number of members shall not affect the continuance in office of, and the performance of functions by, any member until the expiry of his term.

Composition of the Provincial Council

A Provincial Council shall, subject to the provisions of sub section (2), consist of the following members namely:
(a) the Secretaries to the Provincial Governments in the Health Department, exofficio, who shall, unless the Provincial Government appoints any other officer to be the President, also be the President of the respective Council; and
(b) The officers, if any, appointed under clause (a) to be the President of the Council;
(c) Five persons to be nominated by the Provincial Government, of whom one shall be an officer of that Government; and
(d) One person to be nominated by the provincial Branch of the Pakistan Pharmacists Association

Disqualification for membership

A person, other than a professor of a medical institution of a pharmacy institution or an officer of the Provincial Government nominated under Clause(c) of sub section (1) of Section 5, shall not be eligible for nomination as a member of the council unless he is a pharmacist registered in Register A;

Provided that, for the purpose of the constitution of the first Council after the Commencement of the Pharmacy (Amendment) Act, 1973, a person who is qualified to be registered as a pharmacist under this Act shall be eligible for such nomination.

Functions of the Central Council

(1) The functions of the Central Council shall be

(a) to approve examinations in pharmacy for the purpose of qualifying persons for registration as pharmacists;

(b) to prescribe the subjects in which approved examinations shall be held;
(c) to approve the courses of study and practical training in pharmacy for the purpose of admission to approved examination;
(d) to prescribe the conditions and procedure for admission of candidates to an approved examination;
(e) to lay down the standard of teaching to be maintained by institutions conducting the approved courses of study;
(f) to prescribe the equipment and facilities to be made available to the students;
(g) to recognize degree or diplomas in pharmacy for the purpose of registration as pharmacists;
(h) to cause inspection of institutions which conduct any courses of study in pharmacy and of the teachings imparted and examinations held by them; and
(i) to do such other acts and things as it may be empowered or required to do by or under this Act.

(2) The Central Council, with the previous approval of the Central Government, may, by notification in the official Gazette, make regulations for the purposes of sub-section (1).

Functions of a Provincial Council

The functions of a Provincial Council shall be
(a) to prepare and maintain registers of pharmacists and apprentices in pharmacy;
(b) to register pharmacists and grant certificates of registration.
(c) to conduct examinations for the purpose of registration as pharmacists; and
(d) to do such other acts and things as it may be empowered or required to do by this Act.

Preparation and maintenance of Registers

(1) The Provincial Council shall prepare or cause to be prepared and maintained the following Registers of Pharmacists and apprentices for the Province, namely:

Register A - in which shall be registered the persons specified in clause (a) of sub-section (1) of section 25;

Register B - in which shall be registered the persons specified in clauses (b) and (c) of the said sub-section; and

Register C - in which shall be registered the apprentices in pharmacy

Provided that the Provincial Council may, with the previous approval of the Provincial Government, discontinue the registration of apprentices in pharmacy and may, with like approval re-open such registration after it has been discontinued and shall, upon such discontinuance or re-opening, publish in the official gazette a notice there of specifying the date of such discontinuance or re-opening.

(2) Every Register prepared and maintained under sub-section (1) shall include the following particulars relating to a person registered, namely

(a) Full name;
(b) Residential address;
(c) Professional address;
(d) Father's name;
(e) Date and place of birth;
(f) Nationality;
(g) Qualification;
(h) Date on which registered; and

(i) such other particulars as may be prescribed by bye-laws.

Qualifications for registration as a pharmacist or as an apprentice in pharmacy

(1) The following persons shall, subject to the provision of sub-section (3), be qualified for registration as pharmacists under this Act, namely;

(a) persons who hold a degree in pharmacy conferred by a University or an institution affiliated thereto, where the degree is recognized by the Central Council;

(b) persons who hold a diploma in pharmacy granted by any institution recognized by the Central Council; and

(c) persons who pass the examination in pharmacy held by a Provincial Council.

(1-a) Subject to the provisions of sub-section (3) during the period of one year from the commencement of the Pharmacy (Amendment) Act 1973, a person who was on the 19th day of June, 1972 to be deemed to be qualified for registration as a Pharmacist shall be deemed to be so qualified; and

(2) The following persons shall, subject to the provisions of sub-section (3) be qualified to be registered as an apprentice in Pharmacy, namely:

(i) an inspector of Drugs and a government Analyst appointed under the Drugs Act, 1940 (XXIII of 1940), if not otherwise eligible for registration;

(ii) a person certified by a Government Hospital to be a qualified compounder and dispenser;

(iii) a person who has been taken as a student or apprentice in Pharmacy by, and produces a certificate to that effect from, a Pharmacist registered in Register "A" and approved for the

purpose, by notification in the official Gazette, by the Provincial Government, and

(iv) a person who is a qualified person within the meaning of rule 65 of the West Pakistan Drugs Rules 1958, if not otherwise eligible for registration.

(3) No person shall be qualified for registration as a Pharmacist or as an apprentice in pharmacy-

(a) if he is of unsound mind and stands so declared by a court; or

(b) if he has been convicted by a court of any offence which in the opinion of the Provincial Council involves moral turpitude.

Punjab Drugs Rules, 2007

NOTIFICATION
No. SO (DC) 814/92 (53) P-II. In exercise of the powers conferred upon him under section 44 of the Drugs Act, 1976 (XXXI of 1976), the Governor of the Punjab, in super-session of the Punjab Drugs Rules 1988, is pleased to make the following rules:

1. Short title and commencement
(1) These rules may be cited as the Punjab Drugs Rules, 2007.

(2) These, except application of the Schedule G on the existing licences, shall come into force at once.

(3) The Schedule G, for the existing licences, shall come into force after ten years from the date of issuance of this notification.

2. Definitions
(1) In these rules:
(a) "Act" means the Drugs Act, 1976 (XXXI of 1976);

(b) "Committee" means a committee of the Board;

(c) "District Board" means a committee of the Provincial Board in a district to be known as the District Quality Control Board;

(d) "Form" means a form mentioned in the Schedule A;

(e) "Government" means the Government of the Punjab;

(f) "Inspector" means a Provincial Inspector appointed under section 17 of the Act;

(g) "Licensing authority" means the Secretary to the Government, Health Department or an officer of the Government duly authorized by the Secretary;

(h) "Medical store" means premises where drugs excluding the drugs specified in the Schedule G are stored, sold or offered for sale;

(i) "Manufacturer' means a manufacturer of a drug;

(j) "Narcotic, psychotropic or controlled drug" mean a drug specified in the Schedule B or the Schedule D;

(k) "Pharmacy" means premises where drugs are stored, sold, compounded, dispensed or prepared on prescription **or** distributed in case of authorized agent of manufacturer, indenter or importer;
(l) "Provincial Board" means the Provincial Quality Control Board;

(m) "Registered medical practitioner" means a medical practitioner registered under the Pakistan Medical and Dental Council Ordinance 1962 (XXXII of 1962);

(n) "Schedule" means a Schedule to these rules;

(o) "Section" means section of the Act;

(q) "Seller" means the seller of a drug; and

(p) "Wholesale" means sale to a person, buying for the purpose of selling again who is the authorized agent of a manufacturer or importer or indenter.

(2) A word or an expression used in these rules but not defined shall mean the same as defined in the Act.

CHAPTER II

PROVINCIAL BOARD, DISTRICT BOARD, GOVERNMENT ANALYST AND INSPECTOR

Provincial Quality Control Board

(1) The Board shall consist of the following:

(a) Secretary to the Government, Health Department, ex-officio member and chairperson;

(b) Additional Secretary (Technical) to the Government, Health Department, ex officio member and vice-chairperson who shall act as chairperson in the absence of the Secretary Health;

(c) Provincial Drugs Controller of the Government or a senior most officer of the Provincial Drugs Control administration who shall be a pharmacy graduate, Health Department, ex-officio member;

(d) a pharmacy professional who holds a graduate or higher degree in Pharmacy and has more than five years professional experience, appointed as a private member by the Government for a term of four years;

(e) a pharmacologist preferably a professor of pharmacology, appointed as a private member by the Government for a term of four years;

(f) a professor of medicine, appointed as a private member by the Government for a term of four years;

(g) District Coordination Officer of a district, ex officio member, in respect of cases pertaining to the district;

(h) Executive District Officer (Health) of a district, ex-officio member, in respect of cases pertaining to the district; and

(i) a pharmacist of the Government, Health Department, in a district, appointed [ ]by the Government for a term of four years who shall be the Secretary of the District Board.

(2) The Government shall appoint a secretary of the Provincial Board, who holds a graduate or higher degree in pharmacy and has at least ten years professional experience who shall also be member of the Provincial Board.

(3) The Government may appoint a pharmaceutical expert and an expert of medicine as members of the Provincial Board in respect of a district for a term of four years.

(4) The quorum for a meeting of the Provincial Board shall be five including the chairperson or vice-chairperson and one member from the concerned district.

(5) No act or proceeding of the Provincial Board shall be invalid merely on the ground of the existence of any vacancy or any defect in the constitution of the Board concerned.

(6) The Board may co-opt any other qualified expert having formal training and experience in the pharmaceutical field.

District Board

(1) Subject to section 11(6) of the Act, the Provincial Board may constitute a committee in a district to be known as the District Quality Control Board comprising the following members:

(a) District Coordination Officer of the district, ex officio member and convener;

(b) Executive District Officer (Health) of the district, ex-officio member;

(c) a pharmaceutical expert in the district appointed by the Government under rule 3(3);

(d) an expert of medicine in the district appointed by the Government under rule 3(3), private member; and

(e) Secretary of the Committee.

(2) The Government shall appoint a Secretary of a District Board who holds a graduate or higher degree in pharmacy and has at least five years professional experience.

(3) The quorum for the meeting of a District Board shall be four including one private member.

(4) A District Board shall perform its functions under the general supervision and subject to the control of the Provincial Board.

(5) The Provincial Board may issue direction or instruction to a District Board.

Procedure for the Board

(1) An Inspector or a Government Analyst shall submit monthly reports on Form 1 and Form 2 to the District and the Provincial Board and a summary of the overall situation of quality control in his area of jurisdiction, the Provincial and the District Board shall maintain the information in order to monitor the quality of all the drugs sold and to review the performance of the manufacturers and the sellers.

(2) The Provincial and the District Board may meet at least once in a month to review the situation of the quality control of drugs on the whole including consideration of any specific point arising during the period on the working of various firms, drug testing laboratories and inspectors.

(3) The Provincial or the District Board shall examine a case referred to it by an Inspector and shall, if an action is proposed to be taken against a person under the Act or the rules, issue a show cause notice to the person and provide him an opportunity for hearing before taking the action about the prosecution of the person or recommending suspension or cancellation of his licence to the licensing authority.

(4) Before referring a case to a Drug Court, the Provincial or the District Board shall ascertain the name of the director, partner and employee of the company, corporation, firm or institution who is prima facie responsible for the commission of the offence under the Act or the rules and may allow an inspector to institute prosecution against such person.

(5) The Provincial or the District Board may, in case of a minor contravention, direct the manufacturer or the seller to bring improvement, issue a warning to him, order the de-sealing and take any other action including recall of batches.

(6) The Provincial and the District Board may forbid a person, for a period not exceeding three months, from removing or disposing of a drug, article or other thing likely to be used as evidence in an offence under the Act or the rules.

Qualifications, etc. of Inspectors and Government Analyst.–

(1) No person shall be appointed as an Inspector unless he holds a degree in Pharmacy from a University or an institution recognized by the Pharmacy Council of Pakistan and has at least one year experience in the manufacture, sale, testing or analysis of drugs.

(2) No person shall be appointed as a Government Analyst unless he holds a degree in Pharmacy from a University or an institution recognized by the Pharmacy Council of Pakistan and has at least three years experience preferably in the manufacture, testing or analysis of drugs.

Duties of Inspectors

Subject to the instructions of the licensing authority, an Inspector shall–

(a) Inspect a medical store, a pharmacy and a drug manufacturing premises at least once in three months and maintain record of the inspections;

(b) Satisfy himself that the conditions of the licence are being observed;

(c) if he has reasons to believe that a drug is being manufactured, sold, stocked or exhibited for sale in contravention of a provision of the Act or the rules, he may take samples of the drug and may send it for test or analysis and may seize the drug or any equipment;

(d) Investigate any complaint made to him in writing against a person and submit a report of his investigation to the Provincial or the District Board;

(e) Initiate prosecution on the direction of the Provincial or the District Board and to pursue cases in the Court;

(f) Maintain record of actions taken by him in the performance of his duties, including the taking of samples and seizure of drugs or equipments, and submit reports of such record to the Provincial and the District Board;

(g) Stop manufacture or sale of drugs being carried in contravention of the Act and these rules; and

(h) Inspect a place licensed under the Act or the rules before renewa of the licence.

Prohibition of disclosure of information

Except for the purpose of official business or when required by a Court, an Inspector or a Government Analyst shall not disclose to any unauthorized person any information acquired by him in the course of his official duties.

Form of order not to dispose off stock

An Inspector, requiring a person not to dispose of a drug or other material, shall make the order under section 18(1)(i) of the Act in Form 3.

Form of intimation of purpose of taking samples

(1) An Inspector who takes sample of a drug for the purposes of test or analysis, shall intimate the purpose of taking the sample to the person from whom he takes the sample in Form 4 and if he seizes a drug or other material, shall issue receipt of the seizure in Form 5.

(2) The Inspector shall send a portion of the sample or the container to the Government Analyst for test and analysis through a memorandum in Form 6.

(3) The Inspector shall send a specimen impression of his seal to the Government Analyst.

Duties of Government Analyst

(1) A Government Analyst shall conduct test and analysis of the sample of a drug sent to him under the Act or the rules and shall furnish report, the result of test and analysis in Form 7.

(2) A Government Analyst shall conduct test and analyses of the sample of a drug sent to him in writing by an Inspector, a Government Department or any other public institution and shall

furnish the report of the result of test and analysis to the Inspector, the Government Department or the public institution.

(3) A Government Analyst shall forward to the Government monthly report containing results of samples tested and analyzed during the month for publication at the discretion of the Government and furnish such other information as may be required by the Government.

Procedure on receipt of samples from Inspectors

On receipt of a sample of a drug from an Inspector, the Government Analyst shall compare the seals on the packet with the specimen impression received and shall note the condition of the seal on the package and after the test and analysis has been completed, he shall forthwith supply to the Inspector and the Board, a report of the result of the test and analysis.

Fee for test and analysis of drugs

(1) A Government Analyst may receive sample of a drug from a person other than Inspector, the Government Department or a governmental Institution.
(2) If the sample of a drug is received from the person, the Government Analyst shall charge fee for the test and analyses of the sample at the rate specified in the Schedule C.

(Note: All types of fee could be changed time to time by Government)

CHAPTER III

Licences under the rules

The licensing authority may issue a licence of a pharmacy or a licence of a medical store.

Application and fee for licence

(1) A person may apply to the licensing authority for the grant or renewal of a licence referred to in rule 14 in Form 8(A) or Form 8(B).

(2) The applicant shall deposit the fee for a licence in the Head of Account No. 1252-Health-Other Receipt, at the following rates:

(a) three thousand rupees for a licence of a pharmacy and two thousand rupees for a licence of a medical store; and

(b) two thousand rupees for renewal of a licence of a pharmacy and one thousand rupees for renewal of a licence of a medical store.

(3) The licensing authority shall issue or renew a licence subject to the conditions prescribed in the Act and the rules.

(4) The applicant shall pay 50% of the fee for change of the qualified person or the duplicate copy of the licence.
(Note: All types of fee could be changed time to time by Government)

Forms of licenses to sell drugs

The licensing authority shall issue a licence of a pharmacy in Form 9 and a licence of a medical store in Form 10.

Sale at more than one place

(1) If a person desires to sell, store, exhibit for sale or distribute drugs at more than one place, he shall apply for a separate licence in respect of each place.

(2) Provision of sub-rule (1) shall not apply in case the drugs are properly stored in a godown, used only for storage of drugs and which meets the storage conditions and is enlisted along with its complete address on the licence.

Duration of licences

(1) A licence issued or renewed under these rules shall unless suspended or cancelled earlier, remain in force for two years from the date of issue.

(2) If a person fails to apply for the renewal of a licence within thirty days after the expiry of the licence, his licence shall stand cancelled.

(3) If a person applies for the renewal of a licence within thirty days after the expiry of the licence, his licence shall remain enforce until an order on the application is passed by the licensing authority.

(4) The licensing authority shall issue a receipt of an application of a licence or renewal of a licence.

(5) The licensing authority shall dispose of an application for a licence or renewal of a licence within 45 days of the receipt of the application.

(6) If the licensing authority fails to dispose of the application within the specified time, it shall record reasons for its failure.

(7) If in the opinion of the licensing authority, it is not expedient in public interest to grant a license, it may refuse the application.

(8) The licensing authority shall not renew a licence without an inspection report of the Inspector.

Conditions for issuance of licences

(1) The licensing authority shall not issue a licence in Form 9 (pharmacy) and Form 10 (medical store) unless-

(a) the premises has proper and adequate facility for storage of drugs and for their protection from direct sunlight, dust or dirt, including refrigeration facility;

(b) the premises is clean, hygienic and in tidy condition;

(c) in the case of a licence of a pharmacy in which preparation or compounding of a drug is undertaken, the premises has fulfilled the requirements contained in the Schedule F;

(d) the covered area of the premises of a pharmacy is not be less than 140 square feet with minimum breadth of 8 feet in the front and height of 8 feet and in case of a medical store, 96 square feet with minimum breadth of 8 feet and height of 8 feet;

(e) the applicant is not a convict who has been sentenced for imprisonment for a period of one year or more or sentenced to pay fine of thirty thousand rupees or more for manufacturing or selling spurious drugs; and

(f) a person who is registered under section 24(1)(a) of the Pharmacy Act 1967 (XI of 1967) has agreed to personally supervise the sale of drugs for licence in Form 9 (pharmacy) and a person who is registered under section 24(1)(a) & (b) of the said
Act has agreed to supervise sale of drugs for licence in Form 10 (medical store).
Provided that provision of this rule for the licences already issued shall come into force after ten years from the notification of these rules**.**

(2) The licensing authority shall not issue a licence without inspection report by a committee comprising of Secretary of the District Board or the Area Drugs Inspector**.**

Conditions of licences

The licensing authority shall issue a licence in Form 9 or Form 10 subject to the conditions stated in the licence and to the following general conditions:

(a) in the case of a pharmacy, the person shall display the word "Pharmacy" outside wall of the pharmacy in white writing on a green coloured signboard having minimum length of 5 feet and width of 2.5 feet and in the case of a medical store, the person shall display the words "Medical Store" in white writing on a blue coloured signboard with the same minimum dimensions as required for a pharmacy;

(b) a person who is registered under section 24(1)(a) of the Pharmacy Act 1967 (XI of 1967) shall personally supervise the sale of drugs under licence in Form 9 (pharmacy) and a person who is registered under section 24(1) of the said Act shall personally supervise sale of drugs under license in Form 10 (medical store);

(c) The supply of a drug shall be recorded suitably and the records, the bills or the counterfoils shall be preserved for a period of at least three years from the date of the sale;

(d) a drug specified in the Schedules B and D and a preparation containing such drug shall not be sold except on and in accordance with the prescription (original to be retained by the pharmacy or the medical store) of a registered medical practitioner; a prescription may be dispensed with in case of an emergency (recorded in writing in the register); and no such prescription shall be required for sale of the drug to a registered medical practitioner, a hospital dispensary or any other institution;

(e) Subject to rule 1, a licensee of a medical store shall not sell or store a drug mentioned in the Schedule G; and

(f) The sale of a drug specified in the Schedules B and D shall be recorded at the time of supply in a register specially maintained for the purpose and the serial number of the entry in the register shall be entered in the prescription, and the following particulars shall be entered in the register:

(i) S. No., (ii) Date of Sale; (iii) Name of the prescriber;
(iv) Name of the patient; (v) Name of the drug;
(vi) Name of the manufacturer; (vii) Quantity sold;
(viii) Batch No; (ix) Signature of the qualified person; and
(x) Quantity purchased and balance.

Cancellation or suspension of licences

The licensing authority may, on the report of an Inspector or the Provincial and the District Board, after giving the licensee an opportunity to show cause and by an order in writing stating the reasons, cancel a licence issued under these rules or suspend it for such period as it deems fit, if in its opinion the licensee has failed to comply with any of the conditions of the licence or with any of the provisions of the Act or these rules.

Provincial Appellate Authority

(1) A person aggrieved by an order of the licensing authority may prefer an appeal to the Provincial Appellate Authority within thirty days of the date of the order.

(2) The Additional Chief Secretary of the Government shall be the Provincial Appellate Authority for the purpose of hearing appeals against an order of the licensing authority.

(3) The Provincial Appellate Authority may direct an officer or an official of the Government to assist the Authority.

(4) The Provincial Appellate Authority shall, after giving the appellant an opportunity of hearing, pass such order as it deems fit and the order of the Authority shall be final and cannot be called in question before any forum.

Conditions Of Licence

1. The person (s) registered under section 24(1) of the Pharmacy Act 1967 (XI of 1967) shall personally supervise the sale of drugs.

2. This license and registration certificate (from pharmacy council) of the person(s), personally supervising the sale of drugs shall be displayed in a prominent place in part of the premises open to the public.

3. The licensee shall comply with the provisions of the Drugs Act, 1976 and the rules framed there under for the time being in force.

4. The licensee shall report forthwith to the Licensing Authority, any change in person (s) incharge, personally supervising the sale of drugs.

5. No drug requiring special storage conditions of temperature and humidity shall be stored or sold unless the precautions necessary for preserving the properties of the contents have been observed throughout the period during which it remained in possession of the licensee.

6. The fee for change of premises or name & title of the business will be the same as that for a new license subject to satisfactory inspection report.

7. The fee for change of premises or name & title of the business will be the same as that for a new license subject to satisfactory inspection report.

8. The licensee shall not sell or store a drug mentioned in the Schedule G.

An Introduction To Management

Introduction To Management

Management Definition

The process of coordinating work activities so that they are completed efficiently and effectively with and through other people.

Purpose/ Objectives Of Management

- Getting Maximum Results with Minimum Efforts
- Optimum utilization of resources
- Minimizing the element of risk
- Improving overall performance
- Planning for the future
- Growth and Development of business
- Better quality goods
- Ensuring regular supply of goods
- Research and Development

Promotion

Promotion is every form of communication used to inform, persuade, and remind the target customers about the products/ services or organization.

We can also define promotion as, all activities that communicate the merits of the product and persuade target customers to buy it.

Objective Of Promotion

- The ultimate objective of promotion is to motivate the customer, build the firm's image and thereby, to increase the sale of its products/ services
- Influence the buyer
- To let the customers know about a product or firm.
- Convincing the customers to select a particular brand from available choice
- To reminding customers about the products

Major Promotion Tools

- Advertising
- Salesmanship/ Personal Selling
- Sales Promotion
- Publicity and Public Relations
- Direct Mail

Advertising

Advertising is the paid form of impersonal mass communication in which the advertiser's name is clearly identified.

We can also say that

Advertising is the non-personal communication of information, usually persuasive in nature, about products/ services/ ideas through various medias.

Companies use advertising to…

- Inform people about their products and services
- To make their brand names familiar to the public

Purposes Of Advertising

- To sell a product or service
- To support salesmanship
- Facilitate sales from channel
- To enter new geographic market
- To introduce new product
- To expand product usage
- Builds awareness of products and brands
- Creates a brand image
- Provides product and brand information
- Persuades people
- Reinforces past purchases and brand experiences
- To build goodwill for company

Major Advertising Media

- Medical Literature
- Professional journals
- Magazine
- Television
- Newspaper
- Radio
- Cinema
- Internet
- Direct mail

Salesmanship/ Personal Selling

Personal selling is the presentation of a product to prospective customers by a representative of a firm.

Sales Management

Sales management is attainment of an organization's sales goals in an effective & efficient manner through

1. **Planning**
2. **Staffing**
3. **Training**
4. **Leading**
5. **Controlling**

Planning

Planning includes decisions about goals and activities that an individual or group will perform and the use of resources needed to achieve the organization's sales goals.

Staffing

It includes hiring the right people to sell and to lead the salespersons.

Training

Educating the sales personnel to satisfy the customers. Pharmaceutical company customers are usually physicians or other health-care professionals. They required more detail as compare to the general public. So the salesman should be well trained.

Leading

Providing guideline or leading the individual or team in the best way so that they can influence other people toward achieving the organization's sales goals.

Controlling

Monitoring sales personnel’s activities, determining whether the organization is on target toward its goals, and making corrections if necessa